ELEPHANT

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20963

Bron
Nationaal Trial Register

Verkorte titel
ELEPHANT

Aandoening

cochlear implant
deafness
clinical trial
tonotopy

cochleair implantaat
doofheid
klinische trial
tonotopie

Ondersteuning

Primaire sponsor: Maastricht University Medical Center+
Overige ondersteuning: Advanced Bionics

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To evaluate the effect of natural place-pitched electric mapping, the following outcome measures will be compared between the new fitting strategy under investigation (Test) and the standard clinical fitting (Control):
- Objective primary outcome: degree of speech understanding (words in quiet, sentences in quiet, sentences in noise) with CI during the first 6 months of rehabilitation.
- Subjective primary outcome: patient preference in daily life for either the natural fitting or clinical fitting during the first 6 months of rehabilitation.
with CI

Toelichting onderzoek

Achtergrond van het onderzoek

In search of the best possible outcome for the severe hearing impaired who have regained the ability to hear by means of a cochlear implant (CI), electrical stimulation and the information it carries should match as closely as possible to what the human brain naturally has evolved to cope with and learned to process instead of relying on plasticity to adapt to an induced mismatch. At the moment, however, CI’s are fitted with a ‘one size fits all’ principle. This is known to cause a mismatch between the frequencies presented by the CI electrode array and the frequencies represented at the corresponding natural acoustic location in an individual cochlea.

In this study it is hypothesized that an individual imaged based fitting that pursues natural hearing alignment and is implemented from the start of the rehabilitation process, will improve the individual outcomes of electric hearing. The natural fitting strategy is thought to give rise to a steeper learning curve, result in a better performance in challenging listening situations, improve sound quality, complement better with residual acoustic hearing in the contralateral ear and win the preference of CI-recipients.

Doel van het onderzoek

In this study it is hypothesized that patients with a cochlear implant will benefit from an individual imaged based fitting that pursues natural hearing alignment and is implemented from the start of the rehabilitation process.

Onderzoeksopzet

This study has multiple phases. The primary part is set up as a prospective single blinded, daily randomized cross-over clinical trial. In this phase electric hearing will be optimized. When patients retain the use of a contralateral hearing aid, acoustic hearing optimization will be performed in a second phase. During the third phase, patients receive their clinical fit, which will be based on the preferences they have obtained during the study period. More in detail, the study outline can be summarized as follows.

- Phase 1. During the intensive CI-rehabilitation phase, mapping of the electrical input will be based on an individualized natural frequency alignment as estimated with imaging methods. This natural fitting will be compared to the standard frequency alignment. A daily randomization scheme will be applied whereby the subject crosses over between CI fitting programs and thus effectively acting as his own control, followed by a period of free choice between both maps to incorporate patient preference. Outcome measures will be assessed at several single points, to address the difference between both CI maps, as well as over time, to address the learning curve with both CI maps.

- Phase 2. After a period of 6 months a stable outcome with CI is expected. When patients retain the use of a contralateral hearing aid up to this time point, the fitting of the acoustic hearing aid will be optimised and compared to the standard fitting. Outcome measures will be assessed acutely and at the end of a take-home period.

- Phase 3. At this time point, patients have indicated their final preference for either the conventional or bimodal HA fitting. In combination with the preferred CI settings, as indicated at the end of phase 1, a clinical fit will be performed for both CI and HA.

Onderzoeksproduct en/of interventie

Two interventions will be implemented during the study.

1. During the intensive CI-rehabilitation phase, mapping of the electrical input will be based on an individualized natural frequency alignment as estimated with imaging methods. This natural fitting will be compared to the standard frequency alignment. A daily randomization scheme will be applied whereby the subject acts as his own control, followed by a period of free choice between both maps. Outcome measures will be assessed at several single points, to address the difference between both CI maps, as well as over time, to address the learning curve with both CI maps.

2. In a second stage, after a stable outcome with CI is reached and if a contralateral hearing aid is used, the fitting of the acoustic hearing aid will be optimised and compared to the standard fitting. Outcome measures will be assessed acutely and at the end of a take-home period.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Adult (18y or older) and meeting the conventional Dutch CI criteria;

• Proficient speaker of Dutch language;

• Post-lingual onset of profound deafness (> 4 years of age);

• Subject receives an Advanced Bionics implant with Midscala electrode and an Advanced Bionics sound processor;

• Prepared to use a study specific hearing aid (Phonak) for the duration of the study;

• Rehabilitation at MUMC+ for the first year after surgery regarding CI as well as HA;

• Active participation in trial related procedures such as daily randomization and regular testing.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Physical or non-physical contraindications for MRI or CT imaging;

• Additional disabilities that may prevent active participation and testing as per protocol. If there are indications that the mental abilities to comply with the study procedures are insufficient, additional screening will be performed with the Mini-Mental State Examination. Patients will be excluded from the study when the resulting score is lower than 24;

• Cochlear or neural abnormalities that could affect outcome measures and/or compromise the placement of the electrode as assessed by the CI surgeon;

• Active participation in another prospective clinical trial;

• Pregnancy at time of imaging;

• Requirement for electric-acoustic activation prior to the first year follow-up;

• Having received a cochlear implant earlier (e.g. explantation or bilateral implantation).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2018

Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52955
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5049
NTR-old	NTR7447
CCMO	NL64874.068.18
OMON	NL-OMON52955

Resultaten